

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
CVS HEALTH CORPORATION**

**I. PREAMBLE**

CVS Health Corporation and its subsidiaries (collectively, “CVS Health”) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). CVS Health is an integrated pharmacy services health care provider engaged in certain business lines that do business with Federal health care programs. Except as otherwise specified herein, the terms of this CIA shall apply to Omnicare, Inc. and its operating subsidiaries, which is CVS Health’s business line of institutional pharmacy services operations (“IPS Operations”), as defined in Section II.C.1, below. Effective August 18, 2015, CVS Health acquired Omnicare, Inc. Contemporaneously with this CIA, Omnicare, Inc. is entering into a Settlement Agreement with the United States.

In consideration of the obligations of CVS Health in this CIA and the obligations set forth in the settlement agreement entered into among the United States of America, acting through the United States Department of Justice and on behalf of the OIG-HHS; Omnicare, Inc.; NCS Healthcare, LLC; NeighborCare, Inc.; and Relators Donald Gale and Marc Silver on June 25, 2014 (hereinafter “2014 Omnicare Settlement Agreement”), OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Omnicare, Inc.; NCS Healthcare, LLC; or NeighborCare, Inc. under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct described in Paragraph F of the 2014 Omnicare Settlement Agreement. OIG expressly reserves all rights to comply with any statutory obligations to exclude Omnicare, Inc.; NCS Healthcare, LLC; or NeighborCare, Inc., and/or their officers, directors, and employees, from Medicare, Medicaid, and all other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct.

CVS Health represents that it has implemented a compliance program (“Compliance Program”) that includes, among other things, a Chief Compliance Officer and a Compliance Committee responsible for compliance oversight. The Compliance Program also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations, and screening measures for Ineligible Persons. CVS Health shall continue the Compliance Program throughout the term of this CIA; shall expand the Compliance Program, as necessary, to cover any parts of the corporation not currently covered that conduct business with Federal health care programs; and shall do so in accordance with the terms of this CIA. CVS Health may modify the Compliance Program as appropriate, but, at a minimum, CVS Health shall ensure that the Compliance Program satisfies the obligations set forth herein during the term of this CIA.

## **II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by CVS Health under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) CVS Health’s final annual report; or (2) any additional materials submitted by CVS Health pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “IPS Operations” shall mean all operations conducted by CVS Health, including, but not limited to, those conducted under the Omnicare and NeighborCare names, relating to institutional pharmacy services, including, but not limited to, the furnishing of pharmacy or patient care items or services to long-term care facilities, mental and behavioral health institutions, developmental disability centers, penal institutions, and government facilities. For purposes of this CIA, IPS Operations does not include the operations conducted by CVS Health’s pharmacy benefit manager, CVS Caremark; CVS Health’s open door retail pharmacies or distribution centers; NovoLogix; Accordant; Coram; CVS Specialty; MinuteClinic; SilverScript; RxCrossRoads; PharmaSource; CVS Health’s Trade group; or any prescription drug plans owned by or operated for the benefit of CVS Health.

2. “Arrangements” shall mean every arrangement or transaction relating to the IPS Operations that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between CVS Health and any actual or potential source of health care business or referrals to CVS Health or any actual or potential recipient of health care business or referrals from CVS Health. The term “source of health care business or referrals” shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom CVS Health refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom CVS Health purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
3. “Focus Arrangements” means every Arrangement relating to the IPS Operations that is between CVS Health and any actual source of health care business or referrals to CVS Health and involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value.
4. “Covered Persons” includes:
  - a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) officers, and directors of CVS Health;
  - b. all employees of CVS Health who are engaged in or have responsibilities relating to the IPS Operations;
  - c. all contractors, subcontractors, agents, and other persons who furnish pharmacy or other patient care items or services relating to the IPS Operations or who perform billing or coding functions relating to the IPS Operations on behalf of CVS Health; and

- d. for purposes of the requirements set forth in Section III.B (Written Standards), Section III.C.1 (Training Plan), Section III.I (Disclosure Program), and Section III.J (Ineligible Persons), all employees, contractors, subcontractors, and agents of CVS Health who are engaged in or have job responsibilities relating to the sale of or billing for items or services payable by the Federal health care programs.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

5. “Arrangements Covered Persons” includes each Covered Person who is involved with the negotiation, approval, execution, or review of CVS Health’s Arrangements relating to the IPS Operations.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

CVS Health shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Responsibilities of Corporate Officers, Compliance Committee, Board of Directors, and Management**

1. *Chief Compliance Officer and Compliance Officer for IPS Operations.* Prior to the Effective Date, CVS Health appointed an employee to serve as its Chief Compliance Officer and shall maintain a Chief Compliance Officer for the term of the CIA. Within 90 days after the Effective Date, CVS Health shall appoint a Compliance Officer for IPS Operations and shall maintain a Compliance Officer for IPS Operations for the term of the CIA. CVS Health’s title for the Compliance Officer for IPS Operations is Vice President and Chief Compliance Officer, Government Programs and Settlements. The Chief Compliance Officer and the Compliance Officer for IPS Operations shall be employees and members of senior management of CVS Health and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for CVS Health. The Chief Compliance Officer shall report directly to the Chief Executive Officer of CVS Health and the Compliance Officer for IPS Operations shall report to the Chief Compliance Officer. The Chief Compliance

Officer and the Compliance Officer for IPS Operations shall be responsible for, without limitation:

- a. overseeing all compliance matters related to CVS Health's IPS Operations;
- b. developing, implementing, and enforcing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- c. making periodic (at least quarterly) reports regarding compliance matters relating to the IPS Operations directly to the Board Committee (defined below) of the Board of Directors of CVS Health, and shall be authorized to report on such matters to the Board Committee at any time. Written documentation of the Chief Compliance Officer and Compliance Officer for IPS Operations' reports to the Board Committee shall be made available to OIG upon request;
- d. monitoring the day-to-day compliance activities engaged in by CVS Health related to the IPS Operations as well as for any reporting obligations created under this CIA;
- e. reviewing and addressing the findings made and internal audits conducted as part of the Risk Assessment and Internal Review Process required by Section III.G; and
- f. reviewing and addressing the Financial Tracking Report of Arrangements created as part of the Risk Assessment and Internal Review Process required by Section III.G.

Any noncompliance job responsibilities of the Chief Compliance Officer or the Compliance Officer for IPS Operations shall be limited and must not interfere with the Chief Compliance Officer's or Compliance Officer for IPS Operations' ability to perform the duties outlined in this CIA.

CVS Health shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer or Compliance Officer for IPS Operations, or any actions or changes that would affect the Chief Compliance Officer's or

Compliance Officer for IPS Operations' ability to perform the duties necessary to meet the obligations in this CIA, within five business days after such a change.

2. Arrangements Officer for IPS Operations. Within 90 days after the Effective Date, CVS Health shall appoint an Arrangements Officer for IPS Operations and shall maintain an Arrangements Officer for IPS Operations for the term of the CIA. The Arrangements Officer for IPS Operations shall be an individual who has experience in negotiating contracts, ensuring compliance with the terms of contracts, and ensuring compliance with the Federal health care program requirements in contractual relationships. The Arrangements Officer for IPS Operations shall be an employee, shall report directly to the Deputy General Counsel, and shall also be accountable to the Compliance Officer for IPS Operations. The Arrangements Officer for IPS Operations shall be authorized to directly report on Arrangements compliance matters to the Board Committee, as defined below, at any time. The Arrangements Officer for IPS Operations shall be responsible for, without limitation:

- a. assisting the Chief Compliance Officer and the Compliance Officer for IPS Operations to develop, implement, and enforce the policies, procedures, and practices to ensure compliance with the Federal health care program requirements in all Arrangements matters relating to the IPS Operations;
- b. developing and conducting training for Arrangements Covered Persons who are engaged in or have responsibilities relating to Arrangements matters involving IPS Operations;
- c. making periodic (at least monthly) reports regarding Arrangements matters involving IPS Operations to the Chief Compliance Officer and the Compliance Officer for IPS Operations. Written documentation of the Arrangements Officer for IPS Operations' reports to the Chief Compliance Officer and the Compliance Officer for IPS Operations shall be made available to OIG upon request;
- d. monitoring the day-to-day Arrangements matters involving IPS Operations activities engaged in by CVS Health;
- e. assisting the Chief Compliance Officer and the Compliance Officer for IPS Operations with reviewing and addressing the findings made and internal audits conducted as part of the

Risk Assessment and Internal Review Process required by Section III.G that relate to Arrangements matters involving IPS Operations; and

- f. assisting the Chief Compliance Officer and the Compliance Officer for IPS Operations with reviewing and addressing the Financial Tracking Report of Arrangements created as part of the Risk Assessment and Internal Review Process required by Section III.G.

3. *Compliance Committee and IPS Operations Compliance Committee.*

Prior to the Effective Date, CVS Health established a corporate compliance committee (“Compliance Committee”). Within 90 days after the Effective Date, CVS Health shall establish an IPS Operations Compliance Committee. The IPS Operations Compliance Committee shall, at a minimum, include the Chief Compliance Officer, the Compliance Officer for IPS Operations, the Arrangements Officer for IPS Operations, and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer for IPS Operations shall chair the IPS Operations Compliance Committee and the Committee shall support the Compliance Officer for IPS Operations in fulfilling his/her responsibilities (e.g., shall assist in the analysis of CVS Health’s risk areas and shall oversee monitoring of internal and external audits and investigations). The IPS Operations Compliance Committee shall meet at least quarterly. The IPS Operations Compliance Committee shall report to the Compliance Committee on a quarterly basis. The minutes of the IPS Operations Compliance Committee meetings and any reports it makes to the Compliance Committee shall be made available to OIG upon request.

CVS Health shall report to OIG, in writing, any changes in the composition of the Compliance Committee or the IPS Operations Compliance Committee, or any actions or changes that would affect the Compliance Committee’s or the IPS Operations Compliance Committee’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of CVS Health (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members. CVS Health’s Board of Directors currently has, and shall maintain during the term of the CIA, an Audit Committee (“Board Committee”).

The Board Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee CVS Health's Compliance Program, including but not limited to the performance of the Chief Compliance Officer, the Compliance Officer for IPS Operations, and the Compliance Committee; and
- b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board Committee summarizing its review and oversight of CVS Health's compliance with Federal health care program requirements and the obligations of this CIA. For the duration of the CVS Caremark CIA the Board Committee may adopt a single resolution summarizing its review and oversight as required by both the CVS Caremark CIA and this CIA.

Each individual member of the Board Committee shall sign a statement indicating that he/she agrees with the resolution. At minimum, the resolution shall include the following language:

“The Board Committee of the Board of Directors has made a reasonable inquiry into the operations of CVS Health's Compliance Program for IPS Operations including the performance of the Chief Compliance Officer, the Compliance Officer for IPS Operations, and the Compliance Committee. Based on its inquiry and review, the Board Committee has concluded that, to the best of its knowledge, CVS Health has implemented an effective Compliance Program for IPS Operations and CVS Health's IPS Operations are in compliance with the Federal health care program requirements and the obligations of the CIA.”

In support of making the resolution above during each Reporting Period, the Board Committee shall submit to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of third party resources, in its oversight of CVS Health's compliance with the Federal health care program requirements and the obligations of this CIA.

If the Board Committee is unable to provide such a conclusion in the resolution, the Board Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to ensure that CVS Health implements an effective Compliance Program.

CVS Health shall report to OIG, in writing, any changes in the composition of the Board Committee, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

5. Management Certifications. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain CVS Health employees (Certifying Employees) shall monitor and oversee activities within their areas of authority and shall annually certify that the applicable CVS Health department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following (or if titles change, the employees with the same responsibilities): the President of Omnicare Division; Senior Financial Officer, Omnicare Division; Senior Vice President, Clinical, Omnicare Division; Vice President of Strategy and Product Innovation, Omnicare Division; Vice President of Sales, Omnicare Division; Senior Director, National Sales of Omnicare Division; Vice President of Account Management, Omnicare Division; Vice President of Finance Operations; Vice President of Billing and Collections, Omnicare Division; Vice President, Internal Operations LTC; Vice Presidents of Operation, Omnicare Division (currently Midwest, West, Southeast, Northeast, and South); Vice President of Internal Operation, Omnicare Division; Associate General Counsel for Contracting, Omnicare Division; Senior Human Resources Business Person, Omnicare Operations; Vice President of Compliance Operations, Omnicare Division; Compliance Officer for IPS Operations; and the Arrangements Officer for IPS Operations. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and CVS Health policies relating to IPS Operations, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of CVS Health that deals with IPS Operations is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. Additionally, I have ensured that all Reportable Events of which I have knowledge have been reported to the Compliance Officer for IPS Operations. I understand that this certification is being provided to and relied upon by the United States.”

Additionally, the Senior Financial Officer, Omnicare Division; Vice President of Finance Operations; and the Vice President of Billing and Collection, Omnicare Division shall include in his/her certifications the following statements in addition to the above language for all Certifying Employees:

“I have taken steps to ensure that CVS Health’s IPS Operations division is tracking, collecting, and taking appropriate action on payments to and from long-term care facilities. I also have taken steps to ensure that CVS Health’s IPS Operations division is tracking discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, and aging of balances in its contracts with long-term care facilities and has fulfilled the obligations of the Corporate Integrity Agreement, and CVS Health policies relating to IPS Operations. I understand that this certification is being provided to and relied upon the United States.”

Additionally, the Vice President of Sales, Omnicare Division; Vice President of Account Management, Omnicare Division; and each Regional Vice President, Omnicare Division shall include in his/her certification the following statements in addition to the above language for all Certifying Employees:

“During the current Reporting Period, I have been involved in the negotiations and execution of new or renewed Arrangements relating to the IPS Operations on behalf of CVS Health. My responsibilities include ensuring that Arrangements matters relating to the IPS Operations, including, but not limited to, Arrangement negotiations, performance, and enforcement, are in compliance with all applicable Federal health care program requirements, including the Anti-Kickback Statute. I have taken steps to promote compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement in the negotiations and execution of the new and renewed Arrangements relating to the IPS Operations. During the current Reporting Period, I also have been involved with the implementation of and/or performance under existing Arrangements relating to the IPS Operations. I have taken steps to promote compliance with all applicable Federal health program requirements and the Corporate Integrity Agreement in the implementation of and/or performance of existing Arrangements relating to the IPS Operations. I understand that this certification is being provided to and relied upon the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he/she is unable to provide the certification above.

Within 90 days after the Effective Date, CVS Health shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this Section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

6. Arrangements Officer for IPS Operations Accountability and Certification. In addition to the responsibilities set forth in this CIA for all Covered Persons and Arrangements Covered Persons, the Arrangements Officer for IPS Operations shall ensure that all Arrangements matters relating to the IPS Operations, including, but not limited to, Arrangement negotiations, performance, and enforcement, are in compliance with Federal health care program requirements. For each Reporting Period, the Arrangements Officer for IPS Operations shall sign certifications that state:

“My responsibilities include ensuring that Arrangements matters relating to the IPS Operations, including, but not limited to, Arrangement negotiations, performance, and enforcement, are in compliance with all applicable Federal health care program requirements, including the Anti-Kickback Statute. During the current Reporting Period, I have reviewed new or renewed Arrangements relating to the IPS Operations on behalf of CVS Health. I have taken steps to promote compliance with all applicable Federal health care program requirements in the negotiations and execution of the above listed new and renewed Arrangements relating to the IPS Operations. During the current Reporting Period, I also have monitored the implementation and enforcement of and performance under the existing Arrangements relating to the IPS Operations. I have taken steps to promote compliance with all applicable Federal health care program requirements in the implementation and enforcement of and performance under the existing Arrangements relating to the IPS Operations. I understand that this certification is being provided to and relied upon by the United States.”

The Arrangements Officer for IPS Operations also shall provide a certified written narrative describing the specific process he/she took to conduct a comprehensive assessment of whether the Arrangements matters relating to the IPS Operations were in compliance with all applicable Federal health care program requirements. If the Arrangements Officer for IPS Operations is unable to provide such a certification and certified written narrative, the Arrangements Officer for IPS Operations shall provide a

written explanation of the reasons why he/she is unable to provide the certification and certified written narrative outlined above.

Within 120 days after the Effective Date, CVS Health shall develop, implement, and enforce a specific written process (“Arrangements Officer for IPS Operations Accountability and Certification Process”) by which the Arrangements Officer for IPS Operations shall perform a comprehensive assessment of whether the Arrangements matters relating to the IPS Operations are in compliance with all applicable Federal health care program requirements. Further reviews shall be conducted to ensure compliance with all applicable Federal health care program requirements in the process of negotiations, execution and performance. A process of subcertification by the appropriate business personnel will be created to ensure that all Arrangements are presented for legal review prior to and during negotiation, execution, and performance. The Arrangements Officer for IPS Operations shall provide a copy of the Arrangements Officer for IPS Operations Accountability and Certification Process to the IPS Operations Compliance Committee, the Compliance Committee, the Board Committee of the Board of Directors, and OIG. All subcertifications relied on by the Arrangements Officer for IPS Operations shall be made available to OIG upon request

B. Written Standards

Within 90 days after the Effective Date, CVS Health shall develop and implement written policies and procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and CVS Health’s compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law).

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, CVS Health shall enforce its Policies and Procedures and shall make compliance with its Compliance Program, including the Compliance Program requirements outlined in this CIA and CVS Health’s compliance with Federal

health care program requirements an element of evaluating the performance of each employee.

At least annually (and more frequently, if appropriate), CVS Health shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Training Plan.* To the extent not already implemented, within 90 days after the Effective Date, CVS Health shall develop a written plan (Training Plan) that outlines the steps CVS Health will take to ensure that: (a) all Covered Persons receive adequate training regarding CVS Health's CIA requirements and Compliance Program, including the Code of Conduct (General Training) and (b) all Arrangements Covered Persons receive adequate training regarding: (i) Arrangements and practices (e.g., discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, and aging of balances) that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute; (ii) CVS Health's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of CVS Health's Arrangements to know the applicable legal requirements and the CVS Health's Policies and Procedures; (iv) the legal sanctions under the Anti-Kickback Statute; and (v) examples of violations of the Anti-Kickback Statute.

The Training Plan shall include information regarding the training topics, the identification of Covered Persons and Arrangements Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of CVS Health's Training Plan, OIG will notify CVS Health of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, CVS Health shall implement its Training Plan. CVS Health shall furnish training to its Covered Persons and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

As of the Effective Date, to the extent that General Training provided to Covered Persons under the CVS Caremark CIA has already occurred for the calendar year, OIG shall credit the training towards the General Training obligations for those Covered Persons who received training as described above by notifying the Covered Persons of the fact that CVS Health has entered into a second CIA and notifying them of the CVS Health's requirements under the CIA.

2. *Board Member Training.* Within 120 days after the Effective Date, CVS Health shall provide at least two hours of training to each member of the Board of Directors. This training shall address CVS Health's CIA requirements and Compliance Program (including the Code of Conduct), the corporate governance responsibilities of board members, the responsibilities of board members with respect to review and oversight of the Compliance Program, and compliance risk areas specific to the IPS Operations. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity involved in IPS Operations. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

3. *Training Records.* CVS Health shall make available to OIG upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

4. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he/she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials.

5. *Qualifications of Trainer.* Persons providing or preparing the training shall be knowledgeable about the subject area.

6. *Update of Training Plan.* CVS Health shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the Arrangements Review, or the Additional Items Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the

OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to CVS Health's Training Plan, OIG will notify CVS Health of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, CVS Health may implement the revised Training Plan.

7. *Computer-based Training.* CVS Health may provide the training required under this CIA through appropriate computer-based training approaches. If CVS Health chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Compliance with the Anti-Kickback Statute

1. *Focus Arrangements Procedures.* Within 120 days after the Effective Date, CVS Health shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to this statute (Focus Arrangements Procedures). These procedures shall include, but are not limited to, the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and using financial databases to track financial transactions and the information specified in III.D.1.b-g below for each existing and new or renewed Focus Arrangement ("Focus Arrangements Database");
- b. tracking the names and positions of the Arrangements Covered Persons involved in the original negotiations for all new or renewed Focus Arrangements, the Arrangements Covered Persons involved in the original negotiations for all existing Focus Arrangements if available, the Regional Vice President(s) with oversight over the Focus Arrangement, and the lawyer who reviewed and approved the Focus Arrangements (the names and positions of the Arrangements Covered Persons involved with financial aspects of the of the Focus Arrangement shall be made available to OIG or the IRO upon request);

- c. tracking remuneration to and from all parties to Focus Arrangements;
- d. tracking all discounts (e.g., prompt pay discounts, electronic payment discounts), write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements related to any Focus Arrangement, and aging of balances;
- e. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- f. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
- g. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute to ensure the Focus Arrangements are legally compliant, (ii) a financial review and tracking of all Focus Arrangements to ensure that the parties are complying with the financial terms of the agreement and tracking the remuneration in accordance with the terms of the agreement, (iii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iv) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;
- h. requiring the Chief Compliance Officer, Compliance Officer for IPS Operations, and Arrangements Officer for IPS Operations to review the Focus Arrangements Database, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the IPS Operations Compliance Committee and the Compliance Committee; and

- i. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Sections III.L and III.M when appropriate.

2. *New or Renewed Focus Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, CVS Health shall comply with the following requirements (Focus Arrangements Requirements):

- a. ensure that each Focus Arrangement is set forth in writing and signed by CVS Health and the other parties to the Focus Arrangement;
- b. include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete at least one hour of training regarding the Anti-Kickback Statute and examples of arrangements that potentially implicate the Anti-Kickback Statute. Additionally, CVS Health shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Anti-Kickback Statute Policies and Procedures; and
- c. include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* CVS Health shall retain and make available to OIG, upon request, the Focus Arrangements Database, financial systems, and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Accurate Prescription Drug Labeling and Dispensing Systems and Procedures

Within 150 days after the Effective Date, CVS Health shall create systems and procedures reasonably designed to ensure the accurate labeling, tracking, dispensing, and billing of the drug name and manufacturer to the Federal health care programs of

prescription drugs dispensed or used in connection with the IPS Operations. These systems and the procedures shall include, but are not limited to, the following:

1. tracking patient prescription drug information, including information about what specific drug, manufacturer, strength, and dosage was provided to each individual patient, for the purpose of identifying patients impacted by recalls, market withdrawals, and safety alerts; and

2. establishing and implementing a schedule of routine audits of the Automated Label Verification system and any other automated prescription labeling and dispensing system used in IPS Operations to ensure accurate prescription drug labeling, tracking, dispensing, and billing to the Federal health care programs.

F. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, CVS Health shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.F. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and CVS Health shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and CVS Health) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.F affects CVS Health’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Additional Items Review.* In addition to the Arrangements Review, during the five years of the CIA, the IRO shall review up to five additional areas or practices of CVS Health related to the IPS Operations identified by OIG in its discretion (“Additional Items Review”) and shall prepare an Additional Items Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

- a. On a yearly basis, in the Annual Report, CVS Health shall provide to OIG a list of the risk reviews it has performed during the Reporting Period. OIG shall, in its discretion, request and receive the audit report and any requested supporting materials.
- b. In its discretion, OIG may request that CVS Health perform one additional risk review in any Reporting Period, and provide the report to OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to CVS Health a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.F and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

G. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, CVS Health shall develop and implement a centralized annual Risk Assessment and Internal Review Process to identify and address risks associated with Arrangements (as defined in Section II.C.2 above), including, but not limited to, compliance risks specific to: (1) the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and the regulations and other guidance documents related to this statute; (2) the negotiation of new and renewed Arrangements with long-term care facilities and specialty pharmacies; (3) collections pursuant to all Arrangements relating to the IPS Operations and the application or provision of discounts, write-offs, debt forgiveness, short-pays, accounts receivables receivable, collection efforts, settlements, aging of balances; (4) the operations under, and monitoring of, existing Arrangements with long-term care facilities; and (5) per-diem Arrangements with long-term care facilities. The Risk Assessment and Internal Review Process shall require compliance, legal, finance, and department leaders, at least annually, to: (1) identify and prioritize

risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed and reviews conducted by the IRO, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans.

As part of the Risk Assessment and Internal Review Process, CVS Health also shall: (1) make annual findings as to whether the Disclosure Program (as described in Section III.I of this CIA) disclosures are appropriately investigated and resolved; (2) make annual findings as to whether the reporting and repayment obligations are complied with in accordance with Section III.L (Repayment of Overpayments) and Section III.M (Reportable Events) of this CIA; and (3) create a Financial Tracking Report of Arrangements that continually tracks overdue accounts with long-term care facilities, including, but not limited to tracking discounts, write-offs, debt forgiveness, short-pays, accounts receivables receivable, collection efforts, settlements, and aging of balances and report (at least quarterly) on the status of such account balances and debts to the IPS Operations Compliance Committee; the CVS Omnicare Leadership Team (or equivalent leadership group); Senior Finance Officer, Omnicare Division; and Accounts Receivable Department. CVS Health shall maintain the Risk Assessment and Internal Review Process for the term of the CIA.

#### H. Executive Financial Recoupment Program

Within 90 after the Effective Date, CVS Health shall establish a financial recoupment program as outlined in Appendix C to this CIA, which is incorporated by reference, that puts at risk of forfeiture and recoupment an amount equivalent to up to three years of incentive compensation (e.g., annual performance pay, annual bonuses, and long-term incentives) for a Covered Executive, as defined in Appendix C, who is discovered to have been involved in any significant misconduct or who had responsibility for subordinates who were involved in any significant misconduct (“Executive Financial Recoupment Program”). CVS Health shall maintain the Executive Financial Recoupment Program consistent with the specific terms and conditions of Appendix C for the term of the CIA. The Executive Financial Recoupment Program shall apply both to Covered Executives who are current CVS Health employees and to Covered Executives who are former CVS Health employees at the time of a Recoupment Determination, as defined in Appendix C.

#### I. Disclosure Program

To the extent not already implemented, within 90 days after the Effective Date, CVS Health shall establish a Disclosure Program that includes a mechanism (e.g., a toll-

free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer, Compliance Officer for IPS Operations, or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CVS Health's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. CVS Health shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, through a posting on CVS Health's intranet or other internal website available to all Covered Persons, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he/she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, CVS Health shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

#### J. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an "Ineligible Person" shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

- ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* To the extent not already implemented, CVS Health shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. CVS Health shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. CVS Health shall screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. CVS Health shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.J affects CVS Health’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. CVS Health understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that CVS Health may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an

excluded person regardless of whether CVS Health meets the requirements of Section III.J.

3. *Removal Requirement.* If CVS Health has actual notice that a Covered Person has become an Ineligible Person, CVS Health shall remove such Covered Person from responsibility for, or involvement with, CVS Health's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If CVS Health has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or, CVS Health shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

#### K. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, CVS Health shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to any member of senior management of CVS Health conducted or brought by a governmental entity or its agents involving an allegation that CVS Health has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. CVS Health shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

#### L. Overpayments

1. *Definition of IPS Overpayments.* For purposes of this CIA, an "IPS Overpayment" shall mean the amount of money CVS Health's IPS Operations have received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* To the extent not already implemented, within 90 days after the Effective Date, CVS Health shall develop and implement written Policies and Procedures regarding the identification, quantification and repayment of IPS Overpayments received from any Federal health care program.

M. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” shall mean anything that involves:

- a. a substantial IPS Overpayment;
- b. a matter involving IPS Operations that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.J.1.a; or
- d. the filing of a bankruptcy petition by CVS Health.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If CVS Health determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, CVS Health shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.M.1.a.* For Reportable Events under Section III.M.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial IPS Overpayment exists and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by CVS Health to identify and quantify the IPS Overpayment; and
- d. a description of CVS Health's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an IPS Overpayment, within 60 days of identification of the Overpayment, CVS Health shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.M1.b.* For Reportable Events under Section III.M.1.b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of CVS Health's actions taken to correct the Reportable Event and prevent it from recurring; and
- e. if the Reportable Event has resulted in an IPS Overpayment, a description of the steps taken by CVS Health to identify and quantify the IPS Overpayment.

5. *Reportable Events under Section III.M.1.c.* For Reportable Events under Section III.M.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion Lists screening that CVS Health completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was discovered; and
- d. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.M.1.d.* For Reportable Events under Section III.M.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of Section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by CVS Health to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If CVS Health identifies a probable violation of the Stark Law and repays the applicable IPS Overpayment directly to the CMS contractor, then CVS Health is not required by this Section III.M to submit the Reportable Event to CMS through the SRDP.

8. *Cooperation with OIG.* CVS Health agrees to cooperate with OIG in any investigation of individual CVS Health current and former employees and Covered Persons related to a Reportable Event. Cooperation with OIG pursuant to this Section shall mean compliance with the cooperation requirements of Section III.N.

N. Cooperation in Government Investigations

CVS Health shall cooperate fully and truthfully with all investigations by the United States related to conduct involving the IPS Operations, including the time period prior to when CVS Health acquired Omnicare Inc. on August 18, 2015. CVS Health understands that full cooperation includes: (1) prompt and truthful disclosure to the United States of all matters relating to any potential violations of the Federal or state health care laws by individuals or entities in the pharmaceutical and long-term care industries; and (2) testimony in any administrative hearing and/or court proceeding. CVS Health, upon reasonable notice, shall make reasonable efforts to facilitate access to, and encourage the cooperation of, its directors, officers, managers, members, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. CVS Health further agrees to furnish to the United States, upon reasonable request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the IPS Operations that it has undertaken, or that has been performed by another on its behalf.

**IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, CVS Health proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or proposed purchase, CVS Health wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, CVS Health must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

## V. IMPLEMENTATION AND ANNUAL REPORTS

### A. Implementation Report

Within 150 days after the Effective Date, CVS Health shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Chief Compliance Officer, the Compliance Officer for IPS Operations, and the Arrangements Officer for IPS Operations required by Section III.A, and a summary of other noncompliance job responsibilities the Chief Compliance Officer, the Compliance Officer for IPS Operations Officer, and the Arrangements Officer for IPS Operations may have;
2. the names and positions of the members of the IPS Operations Compliance Committee and the Compliance Committee required by Section III.A.3;
3. the names of the Board members who are members of the Board Committee who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.4;
4. the names and positions of the Certifying Employees required by Section III.A.5;
5. a copy of CVS Health's Code of Conduct;
6. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);
7. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
8. a description of (a) the Focus Arrangements Database required by Section III.D.1.a, (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;
9. a description of the Accurate Prescription Drug Labeling and Dispensing Systems and Procedures required by Section III.E;

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between CVS Health and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to CVS Health;
11. a description of the Risk Assessment and Internal Review Process required by Section III.G;
12. a description of CVS's Executive Financial Recoupment Program required by Section III.H;
13. a description of the Disclosure Program required by Section III.I;
14. a certification that CVS Health has implemented the screening requirements described in Section III.J regarding Ineligible Persons, or a description of why CVS Health cannot provide such a certification;
15. a copy of CVS Health's Policies and Procedures regarding the identification, quantification and repayment of Overpayments required by Section III.L;
16. a list of all of CVS Health's locations relating to the IPS Operations (including locations and mailing addresses), excluding retail pharmacies, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which CVS Health currently submits claims;
17. a description of CVS Health's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
18. the certifications required by Section V.C.

B. Annual Reports

CVS Health shall submit to OIG annually a report with respect to the status of, and findings regarding, CVS Health's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer, the Compliance Officer for IPS Operations, and the Arrangements Officer for IPS Operations; any change in the membership of the IPS Operations Compliance Committee and the Compliance Committee described in Section III.A.3, any change in the Board members who are part of the Board Committee who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.4, and any change in the group of Certifying Employees described in Section III.A.5;
2. the dates of each report described in Sections III.A.1 and III.A.2 made by the Chief Compliance Officer, the Compliance Officer for IPS Operations, or the Arrangements Officer for IPS Operations to the Board Committee (written documentation of such reports shall be made available to OIG upon request);
3. the Board resolution required by Section III.A.4 and a description of the documents and other materials reviewed by the Board or the Board Committee, as well as any additional steps taken, in its oversight of the Compliance Program and in support of making the resolution;
4. the written process for Certifying Employees to follow for the purpose of completing the certification as required by Section III.A.5;
5. the Arrangements Officer for IPS Operations Accountability and Certification Process that the Arrangements Officer for IPS Operations shall follow for the purpose of completing the certification as required by Section III.A.6;
6. the names and positions of each Regional Vice President who executed an Arrangement on behalf of CVS Health relating to the IPS Operations during the Reporting Period;
7. a summary of any changes or amendments to CVS Health's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

8. a copy of CVS Health’s Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which CVS Health ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

9. a description of (a) any changes to the Focus Arrangements Database required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a description of any changes to the requirements of the Accurate Prescription Drug Labeling and Dispensing Systems and Procedures required by Section III.E;

11. a complete copy of all reports prepared pursuant to Section III.F and a copy of the IRO’s engagement letter;

12. a description of CVS Health’s corrective action plan(s) related to issues raised by the Arrangements Review Report or Additional Items Review Report; CVS Health’s written responses to the IRO’s observations, findings, and recommendations in the Arrangements Review Report or Additional Items Review Report, stating what action CVS Health took in response to each observation, finding, and recommendation or why CVS Health has elected not to take action based on the observation, finding or recommendation; and a list of the risk reviews CVS Health has performed during the Reporting Period pursuant to Section III.F.3.a.

13. a summary and description of any and all current and prior engagements and agreements between CVS Health and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to CVS Health;

14. a description of the Risk Assessment and Internal Review Process required by Section III.G., a summary of any changes to the process and a description of the reasons for such changes;

15. a copy of the annual findings and the quarterly Financial Tracking Report of Arrangements required by Section III.G;

16. a summary of all internal audits performed pursuant to Section III.G during the Reporting Period and any corrective action plans developed in response to those internal audits. Copies of the internal audit reports and corrective actions plans shall be made available to OIG upon request;
17. a description of any changes to CVS Health's Executive Financial Recoupment Program required by Section III.H and Appendix C;
18. a copy of the annual report to the Board of Directors concerning CVS Health's Executive Financial Recoupment Program, as required by Appendix C;
19. a summary of the disclosures in the disclosure log required by Section III.I that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law (the complete disclosure log shall be made available to OIG upon request);
20. a certification that CVS Health has completed the screening required by Section III.J regarding Ineligible Persons;
21. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.K. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
22. a description of any changes to the Overpayment Policies and Procedures required by Section III.L, including the reasons for such changes;
23. a summary of Reportable Events (as defined in Section III.M) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;
24. a description of all changes to the most recently provided list of CVS Health's locations relating to the IPS Operations (including addresses) as required by Section V.A.16; and
25. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, CVS Health shall include the certifications of Certifying Employees as required by Section III.A.5;
2. *Arrangements Officer for IPS Operations.* In each Annual Report, CVS Health shall include the certifications of the Arrangements Officer for IPS Operations as required by Section III.A.6;
3. *Chief Compliance Officer, Compliance Officer for IPS Operations, and President of the Omnicare Division.* The Implementation Report and each Annual Report shall include a certification by the Chief Compliance Officer, Compliance Officer for IPS Operations, and the President of the Omnicare Division that:
  - a. to the best of his/her knowledge, except as otherwise described in the report, CVS Health is in compliance with all of the requirements of this CIA;
  - b. to the best of his/her knowledge, CVS Health has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, including the Focus Arrangements Procedures required in Section III.D of the CIA;
  - c. to the best of his/her knowledge, CVS Health has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;
  - d. to the best of his/her knowledge, CVS Health has implemented procedures reasonably designed to ensure the accurate labeling and dispensing of prescription drugs related to the IPS Operations as required in Section III.E; and
  - e. he/she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.
4. *Senior Financial Officer for Omnicare.* The first Annual Report shall include a certification by the Senior Financial Officer for the Omnicare Division, to the best of his/her knowledge, CVS Health has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any

previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

CVS Health shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. CVS Health shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

CVS Health:

Chief Compliance Officer  
1 CVS Drive  
Woonsocket, Rhode Island 02895  
Telephone: (401) 765-1500

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by

OIG, CVS Health may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of CVS Health's books, records, and other documents and supporting materials pertaining to IPS Operations and/or conduct on-site reviews of any of CVS Health's locations for the purpose of verifying and evaluating: (a) CVS Health's compliance with the terms of this CIA; and (b) CVS Health's IPS Operations' compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by CVS Health to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of CVS Health's Covered Persons or employees who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. CVS Health shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. CVS Health's employees may elect to be interviewed with or without a representative of CVS Health present.

## **VIII. DOCUMENT AND RECORD RETENTION**

CVS Health shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs for IPS Operations and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify CVS Health prior to any release by OIG of information submitted by CVS Health pursuant to its obligations under this CIA and identified upon submission by CVS Health as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, CVS Health shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

CVS Health is expected to fully and timely comply with all of its CIA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, CVS Health and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS Health fails to establish and implement any of the following obligations as described in Sections III and IV:

- a. a Chief Compliance Officer;
- b. a Compliance Officer for IPS Operations;
- c. an Arrangements Officer for IPS Operations;
- d. a Compliance Committee;
- e. an IPS Operations Compliance Committee;
- f. the Board of Directors compliance obligations;
- g. the management certification obligations;
- h. the Arrangements Officer for IPS Operations accountability and certification obligations;
- i. a written Code of Conduct
- j. written Policies and Procedures;
- k. the development and/or implementation of a Training Plan for the training of Covered Persons, Arrangements Covered Persons, and Board Members;

- l. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;
- m. Accurate Prescription Drug Labeling and Dispensing Systems and Procedures;
- n. a Risk Assessment and Internal Review Process as required by Section III.G;
- o. annual findings and the Financial Tracking Report of Arrangements required by Section III.G;
- p. an Executive Financial Recoupment Program;
- q. a Disclosure Program;
- r. Ineligible Persons screening and removal requirements;
- s. notification of Government investigations or legal proceedings;
- t. Policies and Procedures regarding the repayment of IPS Overpayments; and
- u. the repayment of IPS Overpayments as required by Section III.L and Appendix B.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS Health fails to engage and use an IRO, as required by Section III.F, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS Health fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS Health fails to submit any Arrangements Review Report or Additional Items Review Report in accordance with the requirements of Section III.F and Appendix B.

5. A Stipulated Penalty of \$5,000 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS Health fails to submit any corrective action plans related to issues raised by the Arrangements Review Report or Additional Items Review Report or written responses to the IRO's observations, findings, and recommendations stating what action CVS Health took in response to each observation, finding, and recommendation or why CVS Health has elected not to take action based on the observation, finding or recommendation in accordance with the requirements of Section V.B.12.

6. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date CVS Health fails to grant access) for each day CVS Health fails to grant access as required in Section VII.

7. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of CVS Health as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$50,000 for each Reportable Event that is not reported to OIG as required under section III.M, and for each Reportable Event that is not reported in a manner consistent with the requirements of section III.M.

9. A Stipulated Penalty of \$10,000 (which shall begin to accrue on the day after the date the obligation became due) for each day CVS Health fails to cooperate and otherwise satisfy any of the obligations and requirements as described in Section III.M.8 and Section III.N.

10. A Stipulated Penalty of \$1,000 for each day CVS Health fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to CVS Health stating the specific grounds for its determination that CVS Health has failed to comply fully and adequately with the CIA obligation(s) at issue and steps CVS Health shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date CVS Health receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-9 of this Section.

B. Timely Written Requests for Extensions

CVS Health may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely

written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after CVS Health fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after CVS Health receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

### C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that CVS Health has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify CVS Health of: (a) CVS Health's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, CVS Health shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event CVS Health elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CVS Health cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that CVS Health has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by CVS Health to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.M;
- b. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.F, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by CVS Health constitutes an independent basis for CVS Health's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that CVS Health has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify CVS Health of: (a) CVS Health's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* CVS Health shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30-day period, but that: (i) CVS Health has begun to take action to cure the material breach; (ii) CVS Health is pursuing such action with due diligence; and (iii) CVS Health has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, CVS Health fails to satisfy the requirements of Section X.D.3, OIG may exclude CVS Health from participation in the Federal health care programs. OIG shall notify CVS Health in writing of its determination to exclude CVS Health. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of CVS Health’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, CVS Health may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to CVS Health of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, CVS Health shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether CVS Health was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. CVS Health shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders CVS Health to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless CVS Health requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of

OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether CVS Health was in material breach of this CIA and, if so, whether:

- a. CVS Health cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following CVS Health's receipt of the Notice of Material Breach: (i) CVS Health had begun to take action to cure the material breach; (ii) CVS Health pursued such action with due diligence; and (iii) CVS Health provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for CVS Health, only after a DAB decision in favor of OIG. CVS Health's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude CVS Health upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that CVS Health may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. CVS Health shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of CVS Health, CVS Health shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

CVS Health and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. OIG may agree to a suspension of CVS Health's obligations under this CIA based on a certification by CVS Health that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If CVS Health is relieved of its CIA obligations, CVS Health shall be required to notify OIG in writing at least 30 days in advance if CVS Health plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) CVS Health's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E. The undersigned CVS Health signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF CVS HEALTH**

/Elizabeth Ferguson/  
ELIZABETH S. FERGUSON  
Deputy General Counsel  
CVS Health Corporation

10/11/2016  
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa M. Re/  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

10/11/2016  
DATE

/Katie Rose Fink/  
KATIE ROSE FINK  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

10/7/2016  
DATE

/Geeta Taylor/  
GEETA TAYLOR  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

10/7/2016  
DATE

/Mary Riordan/  
MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

10/7/2016  
DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.F of the CIA.

#### A. IRO Engagement

1. CVS Health shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.10 of the CIA or any additional information submitted by CVS Health in response to a request by OIG, whichever is later, OIG will notify CVS Health if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CVS Health may continue to engage the IRO.

2. If CVS Health engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, CVS Health shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by CVS Health at the request of OIG, whichever is later, OIG will notify CVS Health if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CVS Health may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review and Additional Items Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations and other guidance documents related to this statute; and

2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review and Additional Items Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Arrangements Review and Additional Items Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *CVS Health and IRO.* If CVS Health terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, CVS Health must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. CVS Health must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify CVS Health in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. CVS Health shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by CVS Health regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify CVS Health in writing that CVS Health shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. CVS Health must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require CVS Health to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### ARRANGEMENTS REVIEW AND ADDITIONAL ITEMS REVIEW

This Appendix contains the requirements relating to the Arrangements Review and Additional Items Review required under Section III.F of the CIA.

#### **I. Arrangements Review**

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to CVS Health's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If CVS Health materially changes the Arrangements systems, processes, Policies and Procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of CVS Health's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. CVS Health's systems, policies, processes, and procedures with respect to creating and maintaining the Focus Arrangements Database, including a detailed description of the information captured in the Focus Arrangements Database;

2. CVS Health's systems, policies, processes, and procedures for tracking the names and positions of the Arrangements Covered Persons involved in the original negotiations for all new or renewed Focus Arrangements, the Arrangements Covered Persons involved in the original negotiations for all existing Focus Arrangements if available, the Regional Vice President(s) with oversight over the Focus Arrangement, and the lawyer who reviewed and approved the Focus Arrangement;

3. CVS Health's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;

4. CVS Health's systems, policies, processes, and procedures for tracking all discounts (e.g., prompt pay discounts, electronic payment discounts), write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements related to any Focus Arrangement, and aging of balances;

5. CVS Health's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

6. CVS Health's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

7. CVS Health's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

8. CVS Health's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by CVS Health, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and a financial review to ensure that the parties are complying with the financial terms of the agreement and tracking the remuneration in accordance with the terms of the agreement;

9. CVS Health's systems, policies, processes, and procedures for determining and documenting the fair market value of the remuneration specified in all Focus Arrangements;

10. the annual review conducted by the Chief Compliance Officer, Compliance Officer for IPS Operations, and the Arrangements Officer for IPS Operations of and reporting to the Compliance Committee and IPS Operations Compliance Committee on the Focus Arrangements Database, CVS Health's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

11. CVS Health's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

12. CVS Health's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of CVS Health's systems, policies, processes, and procedures relating to the items identified in Section A.1-12 above;

3. findings and supporting rationale regarding weaknesses in CVS Health's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-12 above; and

4. recommendations to improve CVS Health's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-12 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of annual reviews by the IRO of the following categories of Focus Arrangements: (1) 25 Focus Arrangements of a similar type chosen by OIG (e.g., per diem contracts, contracts in a specific geographic region, or contracts with a specific long-term care facility chain), for which OIG may consider proposals submitted by CVS Health, internal risk assessment and audit work conducted by CVS Health or the IRO, and other information known to OIG; (2) 25 existing (performed under for at least one year) Focus Arrangements with long-term care facilities; (3) 25 new (entered into during the Reporting Period) Focus Arrangements with long-term care facilities; and (4) 25 Focus Arrangements relating to CVS Health's IPS Operations that are not included in the previous three categories.

The IRO shall randomly select the specific Focus Arrangements to be reviewed for each of the four categories listed above. The IRO shall assess whether CVS Health has

complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in CVS Health's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement; the names and positions of the Arrangements Covered Persons involved in the original negotiations for all new or renewed Focus Arrangements, the Arrangements Covered Persons involved in the original negotiations for all existing Focus Arrangements if available, the Regional Vice President(s) with oversight over the Focus Arrangement, and the lawyer who reviewed and approved the Focus Arrangements; the relevant terms of the Focus Arrangement (*i.e.*, the items or services to be provided; the amount of compensation; any discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, and aging of balances; the effective date; the expiration date; etc.); and the parties' performance under the Focus Arrangement (*i.e.*, items or services actually provided, amount of payments, dates of payment, amounts owed, discounts, write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, aging of balances, etc.);

2. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and financial review) and obtained the necessary approvals and that such review and approval is appropriately documented;

3. verifying that the remuneration related to the Focus Arrangement is subject to CVS's policies and procedures for determining and documenting the fair market value of the remuneration, that remuneration is properly tracked, and that parties to the Focus Arrangement are complying with the terms of the Focus Arrangement;

4. verifying that any discounts (*e.g.*, prompt pay discounts, electronic payment discounts), write-offs, debt forgiveness, short-pays, accounts receivable, collection efforts, settlements, and aging of balances are tracked, not improper, and provided in accordance with CVS Health's written Policies and Procedures;

5. verifying that the service and activity logs are properly completed and reviewed (if applicable);

6. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items and services are properly monitored (if applicable);

7. verifying that if CVS Health discovered a suspected violation of the Anti-Kickback Statute involving the Focus Arrangement, it implemented an effective response, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

8. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.

a. Review Protocol. A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.

b. Sources of Data. A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.

c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and CVS Health shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from CVS Health after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition,

the IRO shall include a narrative in the Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings.* The IRO's findings with respect to whether CVS Health has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings, and recommendations on possible improvements to CVS Health's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.

E. Specialty Contracts Review. The Specialty Contracts Review shall consist of annual reviews by the IRO of 25 contracts involving specialty pharmacy items and services<sup>1</sup> that Omnicare Specialty Care Group negotiated ("Specialty Contracts"). The Specialty Contracts Review shall expire when there are no contracts in existence that Omnicare Specialty Care Group negotiated.

For the IRO's review of the Specialty Contracts, CVS Health shall provide to the IRO a spreadsheet that lists all contracts involving specialty pharmacy items and services that Omnicare Specialty Care Group negotiated. The IRO shall randomly select the 25 Specialty Contracts to be reviewed. CVS Health shall provide to the IRO those 25 Specialty Contracts and financial information that will assist the IRO in assessing the parties' performance under each Specialty Contract.

The IRO's assessment with respect to each Specialty Contract that is subject to review shall include:

1. verifying that the contract is set forth in writing and signed by all parties;
2. verifying that the contract sets forth the relevant terms, including:
  - (a) the discounts, items, or services to be provided;
  - (b) the amount of compensation;
  - (c) the effective date; and
  - (d) the expiration date;

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<sup>1</sup> Specialty care pharmacy services include, but are not limited to, the furnishing of specialty pharmacy items and services, primarily by mail or third party delivery service, to patients with chronic conditions, acute events, or complex or high cost therapies.

3. verifying that the remuneration related to the Specialty Contract is subject to CVS's policies and procedures for determining and documenting the fair market value of the remuneration, that remuneration is properly tracked, and that parties to the Specialty Contract are complying with the terms of the Specialty Contract;

4. verifying that if CVS Health discovered a suspected violation of the Anti-Kickback Statute involving the Specialty Contract, it implemented an effective response, including disclosing Reportable Events when appropriate; and

5. verifying the parties' performance under the Specialty Contract (*i.e.*, items or services actually provided, amount of payments, dates of payment, amounts owed, discounts, etc.).

F. Specialty Contracts Review Report. The IRO shall prepare a report based on each Specialty Contract Review performed. The Specialty Contracts Review Report shall include the following information:

1. *Review Methodology*.

- a. Review Protocol. A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.
- b. Sources of Data. A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Specialty Contracts Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Specialty Contracts selected as part of the Specialty Contracts Review and CVS Health shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Specialty Contracts. If the IRO accepts any supplemental documentation or materials from CVS Health after the IRO has completed its initial review of the Specialty Contracts (Supplemental Materials), the IRO shall identify in the Specialty Contracts Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental

Materials in its review. In addition, the IRO shall include a narrative in the Specialty Contracts Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings.* The IRO's findings with respect to the Specialty Contracts Review and whether the IRO verified the information listed in the Specialty Contracts Review for each of the randomly selected Specialty Contracts. In addition, the Specialty Contracts Review Report shall include observations, findings, and recommendations on possible improvements to CVS Health's policies, procedures, and systems.

G. IRO Access. The IRO shall have full access to CVS Health's Focus Arrangements Database, Specialty Contracts, any documents necessary to perform the Arrangements Systems Review, Arrangements Transaction Review, and Specialty Contracts Review, and any documents that the IRO determines relevant to fulfilling the IRO's responsibilities under this CIA, including, but not limited to, Policies and Procedures, internal or external audits, reports made by the Chief Compliance Officer, the Compliance Officer for IPS Operations, or the Arrangements Officer for IPS Operations. The IRO shall have immediate access to interview Covered Persons for the purpose of performing the Arrangements Systems Review, Arrangements Transaction Review, and Specialty Contracts Review, provided that interviews are conducted in accordance with all applicable laws and the rights of such individuals.

## **II. Additional Items Review**

A. Additional Items Review. The IRO shall perform the Additional Items Review annually to cover each of the five Reporting Periods. The Additional Items Review performed annually by the IRO shall consist of up to five additional reviews of other areas or practices (Additional Items) of CVS Health related to the IPS Operations identified by OIG in its sole discretion during the five-year term of the CIA. OIG shall determine the appropriate review methodology. The IRO shall perform all components of each Additional Items Review.

1. For purposes of identifying the Additional Items to be included in the Additional Items Review for a particular Reporting Period, OIG may consider: (1) proposals submitted by CVS Health or the IRO at least 120 days prior to the end of each Reporting Period; (2) internal risk assessment, audit, and monitoring work conducted by CVS Health or the IRO; and (3) other information known to OIG. For

example, the Additional Items Review for a particular Reporting Period may include a systems review or claims review of CVS Health's Automated Label Verification system, or other prescription labeling system, as they relate to the IPS Operations.

2. CVS Health may propose to OIG that their internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Additional Items Review. OIG retains sole discretion over whether, and in what manner, to allow CVS Health's internal audit work to be substituted for a portion of the Additional Items Review conducted by the IRO.

3. OIG shall notify CVS Health and the IRO of the nature and scope of the IRO review for each of the Additional Items in the Additional Items Review at least 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or CVS Health shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.

4. *Definitions.* If the Additional Items Review for a particular Reporting Period includes a review of claims, then for the purposes any claims review, the following definitions shall apply:

- a. Overpayment: The amount of money CVS Health's IPS Operations has received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with any claims review performed under this Appendix B.
- b. Paid Claim: A claim submitted by CVS Health's IPS Operations and for which CVS Health has received reimbursement from the Medicare program or a state Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify CVS Health and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. CVS Health, or its IRO on behalf of CVS Health, may submit proposals identifying suggestions for the

subset(s) of Paid Claims to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by CVS Health or its IRO or (2) information furnished to OIG regarding the results of CVS Health's internal risk assessment and internal auditing. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

B. Additional Items Review Report. The IRO shall prepare an Additional Items Review Report as described in this Appendix for each Additional Items Review performed. The following information shall be included in the Additional Items Review Report.

1. *Additional Items Review Methodology*
  - a. Additional Items Review Population. A description of the Population subject to the Additional Items Review.
  - b. Additional Items Review Objective. A clear statement of the objective intended to be achieved by the Additional Items Review.
  - c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Additional Items Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier, State Medicaid agency or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
  - d. Review Protocol. A narrative description of how the Additional Items Review was conducted and what was evaluated.
  - e. Supplemental Materials. A description of any Supplemental Materials.

2. *Statistical Sampling Documentation*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO, if applicable.
- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included, if applicable.
- c. A description or identification of the statistical sampling software package used to select the sample and determine the sample size, if applicable.

3. *Additional Items Review Findings*

- a. Narrative Results: A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Additional Items Review.
- b. Quantitative Results
  - i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by CVS Health (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
  - ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an IPS Overpayment to CVS Health.
  - iii. Total dollar amount of all IPS Overpayments in the Additional Items Review.
  - iv. Total dollar amount of Paid Claims included in the Additional Items Review.
  - v. Error Rate in the Additional Items Review.

- vi. A spreadsheet of the Additional Items results that includes the following information for each Paid Claim: Federal or State health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

4. *Recommendations.* The IRO's report shall include any recommendations for improvements to CVS Health's billing and coding system based on the findings of the Additional Items Review.

5. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Additional Items Review and (2) performed the Additional Items Review.

## APPENDIX C

### EXECUTIVE FINANCIAL RECOUPMENT PROGRAM

This Appendix contains the requirements relating to the Executive Financial Recoupment Program required under Section III.H of the CIA. CVS Pharmacy, Inc. and its affiliates (collectively, the “Company”) have established and shall maintain throughout the term of the CIA an Executive Financial Recoupment Program (“Program”) that puts incentive compensation, which includes annual performance pay, annual bonuses, and long-term incentives, at risk of forfeiture and recoupment for a three-year period. The Program applies to certain designated executives of the Company who are the subject of an Affirmative Recoupment Determination (as defined below).

#### A. Scope of the Program

1. Definition of Misconduct. “Misconduct” means: (i) significant misconduct (i.e., significant violation of an applicable Company policy, law, or regulation) relating to the negotiation, approval, contracting, execution, review, or billing of Arrangements by the Covered Executive (as defined below); or (ii) significant misconduct (i.e., significant violation of an applicable Company policy, law, or regulation) relating to the negotiation, approval, contracting, execution, review, or billing of Arrangements by subordinate employees in the business unit for which the Covered Executive had responsibility that does not constitute an isolated occurrence and that the Covered Executive knew or should have known was occurring.

2. Compensation Covered. The forfeiture and recoupment provisions of the Program apply to the following types of incentive compensation: (i) all or a portion of an annual cash incentive paid during the three year period prior to an Affirmative Recoupment Determination (the “Three Year Look Back Period”) under the Management Incentive Plan (MIP), Executive Incentive Plan (EIP), any similar annual cash bonus plan, or any sales incentive plan; (ii) all or any portion of an equity award (including stock options, restricted stock units (RSU) and RSUs granted in respect of performance-based restricted stock awards (e.g., PBRs)) granted during the Three Year Look Back Period; or (iii) all or a portion of a long-term incentive award (e.g., LTIP) paid during the Three Year Look Back Period, but only to the extent all or a portion of the performance period occurs during the Three Year Look Back Period. This Program shall apply prospectively to equity awards granted or incentive compensation paid on or after January 1, 2017 with respect to performance periods beginning on or after January 1, 2017. Equity awards and incentive compensation described in Paragraph A.2 (i), (ii), and (iii) shall be referred to herein, collectively or individually, as “Award” or “Awards.”

This Program applies to any Covered Executive (defined herein) who is determined (pursuant to the procedures set forth in this Appendix C) to be involved in Misconduct.

**B. Administration of the Program**

The Company shall engage in a standardized, formal process to determine, in its sole discretion, whether Misconduct has occurred and, if so, the extent of Awards that shall be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive or received by a Covered Executive upon the disposition of applicable equity Awards. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination.” A determination that all or a portion of an Award shall be forfeited by or recouped from a Covered Executive shall be referred to as an “Affirmative Recoupment Determination.”

Under this Program, in order to recoup an Award, the Company may: (i) cancel an outstanding Award before it is paid; (ii) recoup an Award paid in cash to such Covered Executive; (iii) void an unvested equity Award owned by the Covered Executive; and/or (iv) recoup from the Covered Executive the value of any vested, exercised or settled equity Award; provided, however, that the Company, in connection with any single Affirmative Recoupment Determination the Company will be entitled to cancel, void, or recoup no more than three years (or three performance cycles, if applicable) of each type of Award.

1. Initiation. The Company shall initiate the Recoupment Determination process upon: (1) discovery of potential significant misconduct that may rise to the level of Misconduct, or (2) written notification by a United States Federal government agency to the Company’s Chief Compliance Officer or Vice President and Chief Compliance Officer, Government Programs and Settlements of a situation that may rise to the level of Misconduct and either occurred in the United States or gives rise to liability relating to Federal health care programs. This written notification shall either identify the Covered Executive(s) potentially involved in Misconduct or provide information (e.g., a description of the alleged misconduct and the applicable time period) to allow the Company to identify the Covered Executive. The Company shall initiate the Recoupment Determination process within 30 days after discovery by the Company, or notification pursuant to Paragraph B.1, of potential Misconduct. Absent extraordinary reasons, the Company shall reach a Recoupment Determination within 90 days after initiation of the determination process.

2. Recoupment Committee. The Recoupment Determination shall be made by a committee of senior executives representing the Compliance, Legal, Internal Controls, Finance and Human Resources groups (the “Recoupment Committee”). The Recoupment Committee may also include members of other functional areas or business groups, as it deems necessary. A Covered Executive shall not participate in the Recoupment Committee while that individual is subject to a Recoupment Determination.

3. Definition of Executives Covered. For purposes of the Program, “Covered Executive” means a Senior Director or above (or equivalent level) whose scope of duty primarily involves IPS Operations. The Program shall apply to both Covered Executives who are current Company employees and to Covered Executives who are former Company employees at the time of a Recoupment Determination. A list of responsible positions is attached to this Appendix C and shall be updated on a yearly basis by the Chief Compliance Officer and Vice President and Chief Compliance Officer, Government Programs and Settlements and provided to the OIG.

4. Determination of Misconduct. As part of the Recoupment Determination process, the Recoupment Committee or appropriate Delegate (as defined below) shall: (i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the alleged Misconduct or any written notifications about potential Misconduct received pursuant to Paragraph B.1, above; (ii) make written findings regarding the facts and circumstances associated with the Misconduct and any written notifications about potential Misconduct received pursuant to Paragraph B.1, above; and (iii) set forth in writing its determinations (and the rationale for such determinations) about: (1) whether Misconduct occurred; (2) the extent of Awards that shall be subject to forfeiture and/or repayment by the Covered Executive, if any; (3) the means that shall be followed to implement the forfeiture and/or secure the recoupment of Awards from the Covered Executive; and (4) the timetables under which the Company will implement the forfeiture and/or attempt to recoup the Awards. For purposes of this Paragraph, a “Delegate” shall refer to the Company personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Program.

5. Implementation. The Company shall modify employment and other contracts and Award plan documents as necessary to provide that Awards for each Covered Executive are at risk of forfeiture or recoupment in accordance with the terms of this Program. In addition, the Company shall implement eligibility, repayment and forfeiture conditions on Awards that shall be designed to survive the separation of a Covered Executive’s employment. To the extent permitted by controlling law, these eligibility, repayment and forfeiture conditions shall survive the payment or grant of the

Covered Executive's Awards and the termination of such Covered Executive's employment for a period of three years from the payment of cash Awards or grant of equity Awards for the performance period in which an Affirmative Recoupment Determination against such Covered Executive was made. If payment or grant of any portion of an Award is deferred on a mandatory or voluntary basis, the Three Year Look Back Period shall be measured from the date the Award would have been paid or granted in the absence of deferral.

If an Affirmative Recoupment Determination is made, the Company shall endeavor to collect repayment of any Award from the Covered Executive through reasonable and appropriate means according to the terms of the applicable Award plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, the Company shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Program, good cause shall include, but not be limited to, the cost to the organization exceeds the amount to be recouped, or the Company's inability to bring such a suit under the controlling law of the relevant jurisdiction.

### **C. Reporting**

The Chief Compliance Officer and Vice President and Chief Compliance Officer, Government Programs and Settlements shall provide an annual report to the Audit Committee of the Board of Directors of the Company about: (i) the number and circumstances of any alleged Misconduct that occurred during the preceding year and any written notifications about potential Misconduct received pursuant to Paragraph B.1, above; (ii) a description of any Recoupment Determinations where Misconduct was deemed to have occurred during the preceding year (including any decision to require or not require forfeiture and/or recoupment from any Covered Executives, the amount and type of any forfeiture and/or recoupment, the means for collecting any recoupment and the rationale for such decisions); and (iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior years. A copy of the annual report shall be provided to the OIG as required under section V.B.18 of the CIA.

### **D. Duration of the Program**

The Company commits, to the extent permitted by controlling law, to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A through C above for at least the duration of the CIA, absent agreement otherwise with the OIG.